Plan for Conducting the
As-Is Assessment at Fermilab

February 2, 2009 through April 30, 2009

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EXECUTIVE SUMMARY

This plan describes the assessment that will be performed to document the current status of Quality Assurance and Contractor Assurance implementation at Fermilab, referred to as the "As-Is" assessment or simply the "As-Is". This assessment is scheduled to be conducted between February 2 and April 30, 2009. The assessment will be conducted under the direction of the Fermilab Office of Quality and Best Practices (OQBP) by selected Quality Assurance Representatives (QARs) and process owners from Fermilab Divisions, Sections and Centers (D/S/Cs) with the assistance of on-site EG&G Quality Assurance staff. The assessment effort is planned to evaluate a number Fermilab major processes sufficient to give Fermilab management a baseline understanding of the extent of current implementation of its contractual commitments to the U.S. Department of Energy (DOE) as specified in DOE Order 414.1C *Quality Assurance* and DOE Order 226.1A *Implementation of DOE Oversight Policy*. Fermilab is also assessing and implementing ANSI/ASQ Z1.13 *Quality Guidelines for Research,* 1999 to ensure the application of quality assurance to scientific research.

The results of this assessment activity will be used to evaluate conformity of Fermilab's major processes to Fermilab's Integrated Quality Assurance (IQA), Integrated Contractor Assurance (ICA) programs, and Quality Guidelines for Scientific Research at Fermilab expectations which were developed to establish DOE's objectives for these programs and for scientific research at Fermilab. The processes to be reviewed were selected by each D/S/C based on risk to the laboratory. The As-Is assessment will document the steps in each process and the existing quality controls and compare existing controls for the activity with a range of available controls recorded in the As-Is Tables (As-Is Tables are derived from Fermilab's Graded Approach Procedure's Tables and additional Contractor Assurance controls.). If gaps are identified between quality controls applied in the current state and controls identified for the desired state Corrective Action Plans (CAPs) will be prepared, approved and implemented by Fermilab management to bridge those gaps. The OQBP will assist the D/S/Cs in closing the CAPs, if requested, and provide independent verification of their closure as part of the QA implementation process. A status of Fermilab's progress in closure of the CAPs will be produced in August, 2009 in preparation for the first QA implementation audit by the DOE, currently scheduled for September 14-18, 2009.

The following sections of this plan provide more details on the As-Is assessment process including resources that will be used to accomplish the Fermilab objectives for this activity.

AS-IS ASSESSMENT PURPOSE & SCOPE

As stated in the Executive Summary, this plan describes the processes and resources that will be used to conduct the Fermilab "As-Is" assessment between February 2 and April 30, 2009. The objective of this effort will be to conduct and document an assessment of the selection of Fermilab major processes listed in the detailed As-Is schedule. The results of this activity will give Fermilab senior management and department heads a good understanding where the Laboratory stands relative to implementation of the Quality Assurance and Contractor Assurance commitments in the prime contract with DOE pertaining to DOE Orders DOE O 414.1C, *Quality Assurance* and DOE 0 226.1A, and *Implementation of DOE Oversight Policy*, and the national consensus standard, ANSI/ASQ Z 1.13, *Quality Guidelines for Research*, 1999, selected by Fermilab for application to its research activities.

BACKGROUND

QARs from each Fermilab D/S/C and EG&G Quality Assurance Engineers (QAE) from the Fermilab QA group participated in the planning of the implementation of the Integrated Quality Assurance program at Fermilab. The following are the objectives and deliverables used to prepare for the As-Is assessment for the start date on February 2, 2009.

As-Is Assessment Objectives

- Augment the OQBP QA staff with additional QAEs for the duration of As-Is assessment
- Identify QARs from each D/S/C and QAEs for QAR Team
- Train all QAR Team members
- Create & deploy a QA awareness strategy throughout Fermilab
- Identify Fermilab's major processes
- Prioritize major processes for the assessment
- Identify existing quality controls
- Identify Fermilab Best Practices
- Evaluate compliance of scientific research to ANSI/ASQ Z1.13
- Identify gaps between existing quality controls "As-Is" and required controls
- Provide Fermilab management with a clear understanding of the current state of compliance
- Resolution of DOE 2006 QA Assessment-Review findings
- Create, approve and implement corrective action plans (CAPS) to bridge any gaps between As-Is and As-Required conditions
- Laboratory-wide review of the following four area's of risk
  - o Inspection & test and control of measurement & test equipment (M&TE)
  - o Managing qualification & training
  - o Item control
  - o Control of documents & records

As Is Assessment Deliverables

- QAE and QAR orientation and training
- Plan for conduct of As-Is Assessment (by end of January, 2009)
- Communication of QA awareness
  - *Fermilab Today* "Director's Corner" publications on QA at Fermilab
  - Director's Letter to all Fermilab Employees
  - Director's Charge to QARs to plan, and conduct the As-Is
  - D/S/C QA communications
  - Other QA awareness media such as posters and management staff meetings
- Identification and hierarchical list of Fermilab's major process
- Documentation of processes to be assessed
- Detailed schedule of As-Is Assessment activities (by end of January, 2009 subject to change as the activities proceed)
- Comparison of processes assessed to IQA & ICA Requirements
- Develop Quality Guidelines for Scientific Research at Fermilab compliant with ANSI/ASQ Z1.13 and the IQA
- Comparison of scientific research to Quality Guidelines for Scientific Research at Fermilab
- Report on the status of all items from the 2006 DOE QA audit of Fermilab
- Report on the status of the Laboratory-wide review of the following four area's of risk
  - Inspection & test and control of measurement & test equipment (M&TE)
  - Managing qualification & training
  - Item control
  - Control of documents & records
- Approved CAPs to bridge quality control gaps identified during the aforementioned comparisons

ASSESSMENT PROCESS DESCRIPTION

The assessment process will be conducted by teams composed of QARs and QAEs working with process owners to determine if their processes are currently implementing the expectations of the IQA, ICA and Quality Guidelines for Scientific Research at Fermilab using the following assessment tools:

- Process flow descriptions, diagrams, mappings, or narratives to determine inputs, outputs, and controls
- As-Is electronic data management tool to document existing process quality controls to As-Is Tables and record relevant process documentation including links to source data
- Other guidance tools such as
  - As-Is Mapping Tool User Instructions
  - Guide on Determining Applicability of Assessment Criteria to Lab D/S/Cs
  - QA & CA Checklists containing questions to assist in determining compliance
  - Checklist for assessing quality in scientific research

Planning & Preparation

- Provide QAR Team with training on conflict management & audits – (complete)
- Identification of processes in the D/S/Cs for As-Is assessment – (complete)
- Briefings for senior management and D/S/C staff describing As-Is activities – (complete)
- Identification of processes owners in the D/S/Cs – (complete)
- <u>Prioritization of processes in the D/S/Cs for As-Is assessment</u> – (complete)
- <u>Create detailed schedule of processes areas to be evaluated</u> (complete)
- Create QA Awareness Strategy throughout Fermilab (on-going)
- Create Tools and Guides and provide training on use for conducting the As-Is – (complete)
- <u>Develop, test and release the As-Is Mapping Tool</u> – (complete)

NOTE: The above underlined items, while complete, are living entities. It is expected that the team will be required to modify the prioritized list of processes and subsequent evaluation schedule based upon conditions found during the As-Is activity. It is also expected, even though the team tested the As-Is Mapping Tool under actual assessment conditions, that the team will encounter situations that will require its modification during the As-Is process.

Description of As-Is Assessment Activity Phases for Documenting Processes

- **Initiation Phase**

  (This is in-process now and recurs throughout the As-Is Assessment)
    o Schedule initial informational / planning meeting(s) with process owners, subject matter experts and/or appropriate departmental management

- **Development Phase**
    o Use preliminary meeting information to understand process and plan Collection Phase

- **Collection Phase**
    o Document processes and their quality controls
        ▪ Integrate 2006 DOE QA audit as applicable
            • Verify closed items
            • Assign open items
    o Return and complete evaluation of process quality controls
    o Enter data into the As-Is tool translating into QA program language
    o Identify potential gaps in quality controls

- **Verification Phase**
  - Verify the accuracy of data entered into the As-Is tool with process owner
  - Review the evaluation of controls and gaps identified with process owner with an eye to consensus
    - Record when consensus was not achieved

- **Corrective Action Phase**
  - Develop and document CAPs to bridge agreed upon gaps (Process Owner)
  - Approve CAPs and forward to the Head of OQBP (D/S/C Head)
  - Track & report status of CAPs locally (QAR & Process Owner)
  - Review the approved CAPs, reconcile differences, and concur (OQBP Head)
  - Verify closure of CAPs as they are completed (QAEs & Quality Manager)
  - Track and report status of CAPs globally (Quality Manager & OQBP Head)

Schedule

Summary Schedule
- January 30, 2009 – Complete As-Is Plan
  - Assignment of QAR/QAE teams, identification of relevant process owners/SME designees
  - As-Is Schedule (to include review, evaluation, report, and parallel corrective action review & assistance, as needed)
  - Identification and prioritization of processes by D/SC for As-Is
- February 2-April 30th, 2009 – Conduct As-Is Assessment.
- March 1-June 15th, 2009 - Corrective Action Plans Approved, OQBP concurrence & Implementation underway

Detailed Schedule
- A detailed weekly schedule is maintained in Microsoft Project

ROLES & RESPONSIBILITIES

The QA program implementation required conscription and alignment of many resources to develop the QA program. Individuals from throughout Fermilab are involved in the development and implementation of the plan.

Laboratory Director – Responsible for implementation of QA; Senior manager providing direction, funding, and support for QA implementation and awareness

Directorate & The Assurance Council – Management support & oversight

Head of OQBP – Designee by the laboratory Director responsible for QA system implementation at Fermilab. Provides periodic status reports to the Laboratory Director, Senior Management & the Assurance Council. Reconciles issues raised during the As-Is. Single point of contact between Fermilab and DOE

EG&G Program Manager – Assists Head of OQBP. Provide periodic status reports to Fermilab and EG&G management. Provide QAE resources. Reconcile issues raised during the As-Is.

D/S/C heads – Designees by the laboratory Director for establishment and compliance with QA requirements in their respective organizations. Provide resources for the As-Is assessment. Reconcile issues raised. Provide implementation support and feedback to the QARs & QAEs.

Quality Assurance Manager – Manage the project. Provide periodic status briefs and reports to the OQBP Head and the EG&G Program Manager. Ensure that plans and documents are aligned with DOE Orders, the IQA, ICA and Quality Guidelines for Scientific Research at Fermilab. Provide guidance & direction to D/S/Cs and QAR Team.

All QAR Team Members – Attend periodic team meetings to share lessons learned and obtain support from the team. Elevate issues to the team as appropriate.

D/S/C Quality Assurance Representatives (QARs) – Conduct,& report local As-Is status. Elevate concerns or issues to QA Manager and D/S/C Head as appropriate

EG&G Quality Assurance Engineers (QAEs) – Provide subject matter expertise to QARs and D/S/C staff on the application of quality controls to Fermilab processes. Assist the OQBP and Quality Assurance Manager with implementation of QA system.

QAR sub-team for science - Individual QARs assigned to engage management in scientific community in the As-Is Assessment & subsequent IQA implementation

Associate Director for Research – Responsible for the documentation and development of a program to implement ANSI/ASQ Z1.13 at Fermilab

Systems Analyst – Develop, release, and maintain software tools. Provide user support.

REFERENCE DOCUMENTS

- Charge to QARs
- Fermilab Director's QA communications
- As-Is Assessment Plan (this document)
- As-Is Assessment Schedule
- Integrated Quality Assurance (IQA)
- Integrated Contractor Assurance (ICA)
- Graded Approach Procedure
- [Quality Guidelines for Scientific Research at Fermilab]
- DOE O 414 *Quality Assurance,*
- DOE O 413 *Contractor Assurance*
- ANSI/ASQ Z1.13
- As-Is Tool Instructions
- As-Is Guides & Checklists
- As-Is Tables of QA & CA controls *Quality Guidelines for Research*
- DOE QA Criteria and Review Approach Documents (CRADs)
- Science checklist questions
- 2006 QA DOE Audit

Table of Revisions

Author	Description	Revision	Date
Jed Heyes	Draft- Template	000 A	01/19/09
Tom King, Kurt Mohr	Added content to the template during a number of QAE meetings	000 A1-A11	01/20/09-01/30/09
Jed Heyes, Larry Lamm	Refined & reconciled with As-Is Guide draft	000 A12	01/30/09
Jed Heyes	Completed and promoted to B for OQBP review	000 B	01/31/09
Jed Heyes	Updated TOC to level 3. Added this table of revisions	000 B1	02/01/09
Jed Heyes	Incorporated changes from Jeff Cotton review	000 B2	02/02/09
Jed Heyes	Promoted to C life cycle for validation upon approval by Bob Grant	000 C	02/03/09